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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,316	12/06/2000	Carlos Schuler	015225-005210US	1043

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NEKTAR THERAPEUTICS
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EXAMINER
MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/731,316	SCHULER ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 21, 23-29, 37-39, 43-49, 51-53, 61, and 62* is/are rejected.

7)☒ Claim(s) *19,20,22,30-36,40-42,50,54-60 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3, 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3, 5-7, 11, 15, 16, 18, 21, 25-29, 38, 39, 45, 51-53, and 61 and are rejected under 35 U.S.C. 102(b) as being anticipated by McGinn et al. WO 99/44663.

2. McGinn et al. teaches a method and system for conditioning a packaged powder, the method comprising: providing a receptacle 104; providing at least one pulse of energy; wherein the pulse providing step further comprises quickly striking the receptacle (pg. 24, lines 8-18); releasing a spring loaded lever (pg. 27, lines 12-19); bending the device and then quickly releasing the receptacle (pg. 22, line 24-25 and pg. 23, lines 1-7); moving the receptacle past an area that temporarily engages a portion of the receptacle (pg. 22, line 24-25 and pg. 23, lines 1-7); wherein the powder is composed of fine particles having a mean size in the range from 0.5 micrometer to about 5 micrometers (pg. 5, lines 14-15); wherein the receptacle further comprises a metallic body having a tube extending from the chamber (pg. 16, lines 12-15); a container having having an enclosure, and wherein the mechanism is coupled to the container, wherein the container comprises a base and a cover that is pivotally coupled to the base (figs. 1 and 2); a coupling arrangement that couples the receptacle to the base (fig. 2); an aerosolization system comprising a mouthpiece 72.

3. Claims 1, 8, 9, 11, 15, 23, 24, 26, 27, 37, 43-45, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Abrams et al. 5694920.

4. Abrams et al. teaches a method and system for conditioning a packaged powder, the method and system comprising: a receptacle 228; providing at least one pulse of energy comprising providing a pulse of vibratory energy (col. 7, lines 42-44); contacting the receptacle with a vibrating piezoelectric transducer (col. 7, lines 42-44); wherein the powder is composed of fine particle having a mean size in the range from about 0.5 micrometers to about 5 micrometers (col. 1, lines 40-43); an aerosolization system comprising a mouthpiece 218.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 4, 17, 46-49, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinn et al.

7. As to claim 4, McGinn et al. teaches the method as in claim 3. It should be noted fails to specifically teach striking the receptacle with an amount of energy of at least about 0.01 lbf-in. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to strike the receptacle at a force strong enough to provide sufficient energy to deaggregate the powder. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

8. As to claim 46-48, McGinn et al. teaches a kit for aerosolizing a powder, comprising: at least one receptacle having an enclosed chamber; and an aerosolization device having an opening. It should be noted that McGinn et al. does not specifically teach instructions. However, it would have been inherent to include instructions for proper use of the kit to insure optimum results.

9. As to claim 49, McGinn teaches a kit as in claim 48, wherein the powder conditioning device comprises a frame and a spring-loaded lever are pivotally coupled to the frame, wherein the lever are is releasable to strike the receptacle.

10. As to claim 62, McGinn fails to teach wherein the pulse of energy is provided within about 100 ms before actuation of the aerosolization system to about 23 ms after the actuation of the aerosolization system. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made provide the pulse of energy during the range set forth in the claim to insure complete inhalation of the medication. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

11. Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over McGinn et al. in view of Gonda et al. 6167880.

12. As to claim 2, McGinn et al. teaches the method as in claim 1. It should be noted that McGinn et al. fails to teach providing the pulse of energy while the powder is sealed within the chamber.

Gonda teaches a common method of providing a pulse of energy in a sealed chamber to deaggregate/aerosolize the powder before inhalation. Therefore it would have been obvious to one of ordinary skill in the art to modify the method of McGinn et al. to include the method step of Gonda et al. to deaggregate/aerosolize the powder before inhalation (col. 41, lines 59-62).

13. Claims 10, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al.

14. As to claims 10 and 13, Abrams et al. teaches the method as in claim 9. It should be noted that Abrams fails to teach vibrating the transducer at a frequency of at least about 10 kHz. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vibrate the transducer at a frequency high enough to provide sufficient energy to deaggregate and/or aerosolize the powder to sufficient size to be inhaled by the user. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

15. As to claim 14, Abrams et al. teaches the method as in claim 1. It should be noted that Abrams fails to teach wherein the receptacle is vibrated for about 0.01 minute to about 10 minutes. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vibrate the receptacle for an amount of time long enough to deaggregate the powder. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant

has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

16. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over McGinn et al. in view of Abrams et al.

17. As to claim 12, McGinn et al. teaches the method as in claim 1. It should be noted that McGinn fails to teach providing at least one pre-conditioning step prior to providing the at least one pulse of energy, wherein the pre-conditioning step comprises vibrating the receptacle for a predetermined period of time.

Abrams et al. teaches a common method of pre-conditioning to provide only deaggregated drug particle are used. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of McGinn et al. to include the method step of Abrams et al. to obtain only smaller sized deaggregated particles (col. 6, lines 18-19).

Claim Objections

18. Claims 19, 20, 22, 30-36, 40-42, 50, 54-60, and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MM
March 5, 2003

WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700